

1
2
3
4
5
6
7
8
9
10 **UNITED STATES DISTRICT COURT**
11 **SOUTHERN DISTRICT OF CALIFORNIA**

12 OBESITY RESEARCH INSTITUTE,
13 LLC,
14 Plaintiff,
15 v.
16 FIBER RESEARCH
17 INTERNATIONAL, LLC, *et al.*,
18 Defendants.

Case No. 15-cv-595-BAS(MDD)

**ORDER DENYING
DEFENDANT’S MOTION TO
EXCLUDE THE REPORT &
TESTIMONY OF DR. LAURA
LERNER**

[ECF No. 189]

19
20 **AND RELATED COUNTERCLAIM.**
21

22 On March 16, 2015, Plaintiff Obesity Research Institute, LLC (“ORI”) filed a
23 Complaint for Declaratory Judgment against Defendant Fiber Research International,
24 LLC (“FRI”) asking the Court to declare that it has no liability under either the
25 Lanham Act, the Federal Food, Drug, and Cosmetic Act (“FFDCA”), California’s
26 Unfair Competition Law (“UCL”), and California’s False Advertising Law (“FAL”).
27 (ECF No. 1.) On April 13, 2015, FRI filed its Answer and Counterclaims. (ECF No.
28 16.)

1 Presently before the Court is FRI's Motion to Exclude the Report and
 2 Testimony of Dr. Laura Lerner, an expert witness for ORI, arguing that Dr. Laura
 3 Lerner is unqualified and her testimony is irrelevant and unreliable. ORI opposes.

4 The Court finds this motion suitable for determination on the papers submitted
 5 and without oral argument. *See* Fed. R. Civ. P. 78(b); Civ. L.R. 7.1(d)(1). For the
 6 following reasons, the Court **DENIES** FRI's motion.

7 8 **I. INTRODUCTION**

9 On March 10, 2015, FRI sent a letter to ORI claiming ORI was in violation of
 10 the Lanham Act and the FFDCA. (Ferrell Decl. Ex. 1, ECF No. 24-4.) FRI alleged
 11 that the glucomannan used in ORI's trademarked Lipozene is not equivalent to the
 12 grade of glucomannan used in Shimizu Chemical Corporation's ("Shimizu")
 13 trademarked Propol.¹ (Ferrell Decl. Ex. 1.) ORI allegedly relied on studies of the
 14 effectiveness of glucomannan in Propol, including the Walsh and the Kaats Studies,
 15 as a basis for marketing the effectiveness of Lipozene.² (*Id.*) FRI contends that the
 16 results of Lipozene are not comparable to the results in the studies because the
 17 glucomannan in Lipozene has a lower viscosity than the glucomannan in Propol. (*Id.*)
 18 Due to the purported differences between the glucomannan in Lipozene and Propol,
 19 FRI asserts that ORI has substantially harmed FRI's business. (*Id.*)

20 In response to FRI's letter, ORI filed a Complaint for Declaratory Judgment,
 21 which resulted in FRI responding with Counterclaims on May 28, 2015. (ECF No. 1,
 22 24.) ORI contends that the studies it relied upon never mentioned what grade of
 23 glucomannan was used and that Lipozene contains the same active ingredients as the
 24 products used in the aforementioned studies. (Non-Retained Expert Witness

25
 26 ¹ FRI has the right to sell Shimizu glucomannan products in the United States, including
 Propol. (Ferrell Decl. Ex. 1.)

27 ² ORI references scientific studies on its website that supposedly "confirm Lipozene's active
 28 ingredient, Glucomannan, is safe and effective for weight loss and fat loss." (Answer & Countercl.
 Ex. 1.) FRI contends that these studies do not support the effectiveness of Lipozene, rather they
 only confirm the effectiveness of Propol. (Answer & Countercl. ¶¶ 33-35.)

Designations (“Witness Designations”) 3:25-4:1-2, ECF. No. 220-5, Ex. 1.) Further, ORI takes the position that “Propol is nothing more than a trade mark” under which Shimizu sells glucomannan. (Witness Designations 4:24-25.)

FRI retained Dr. Thomas Wolver as an expert witness to testify on whether ORI can rely on the scientific studies of glucomannan to make certain representations about Lipozene. (Wolver Report ¶ 6, ECF No. 189-3.) In his report, Dr. Wolver opines that Lipozene has a different effect on the body than Propol clinical strength (“Propol CS”). (Wolver Report ¶ 10.) Therefore, Dr. Wolver believes it is “scientifically inappropriate” for ORI to use the Walsh and the Kaats Studies to substantiate the effectiveness of Lipozene. (Wolver Report ¶ 11.) Further, Dr. Wolver opines that the ingredients used in Lipozene “likely has little or no benefit for weight loss.” (Wolver Report ¶ 12.)

To rebut Dr. Wolver’s testimony, ORI retained Dr. Lerner as an expert witness. (Lerner Report, ECF No. 189-5.) Dr. Lerner’s report first pointed to the fact that neither the Kaats nor Walsh Study purported to use Propol CS. (Lerner Report 3.) Dr. Wolver assumed that Propol CS was used, but has no actual knowledge of what variation was used in the studies. (Lerner Report 3, 9-10.) Dr. Lerner rebuts Dr. Wolver’s conclusion that Lipozene is less effective than Propol by analyzing the results of various peer-reviewed studies. (Lerner Report 13.) Dr. Lerner concludes that there is no basis in either scientific literature or lab testing results to support Dr. Wolver’s conclusion that Lipozene is less effective than the glucomannan tested in the Kaats or the Walsh Studies. (Lerner Report 3, 13.)

II. LEGAL STANDARD

Federal Rule of Evidence 702 governs the admissibility of expert witnesses. Expert witnesses can testify to “scientific, technical, or other specialized knowledge” that will assist the “trier of the fact [in] understand[ing] the evidence or to determine a fact in issue.” Fed. R. Evid. 702.

1 Expert testimony is admissible pursuant to Rule 702 if it is both relevant and
2 reliable. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). Evidence
3 is relevant when it has “any tendency to make the existence of any fact that is of
4 consequence to the determination of the action more probable or less probable than
5 it would be without the evidence.” Fed. R. Evid. 401. Reliability requires that an
6 expert’s testimony “have a reliable basis in the knowledge and experience of his
7 discipline.” *Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 462 (9th Cir.
8 2014) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999)).

9 The inquiry into the admissibility of an expert witness’ testimony does not
10 “require a court to admit or exclude evidence based on its persuasiveness.” *Ellis v.*
11 *Costco Wholesale Corp.*, 657 F.3d 970, 982 (9th Cir. 2011). A trial court will not
12 weigh the correctness of an expert witness, rather the court must determine if the
13 expert’s testimony is reliable. Advisory Committee Notes to Rule 702, 2000
14 Amendments (proponents do not have to show by a “preponderance of the evidence
15 that the assessments of their experts are correct, they only have to demonstrate to the
16 judge by a preponderance of evidence that their opinions are reliable the
17 requirement of reliability is lower than the merits standard of correctness”) (quoting
18 *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994)).

19 A witness is qualified to give expert testimony by her “knowledge, skill,
20 experience, training, or education.” Fed. R. Evid. 702. The qualifications for expert
21 witnesses under Rule 702 should be construed broadly. *See Thomas v. Newton Int’l*
22 *Enters.*, 42 F.3d 1266, 1269 (9th Cir. 1994). It is an abuse of discretion for a court
23 to disqualify an expert witness that is generally qualified. *Id.* (holding court abused
24 discretion by narrowly construing expert witness’ qualifications under Rule 702); *see*
25 *also In re Silicone Gel Breasts Implants Prods. Liab. Litig.*, 318 F. Supp. 2d 879, 889
26 (C.D. Cal. 2004).

27 When considering the admissibility of an expert witness, the court acts as a
28 “gatekeeper” rather than a fact finder. *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir.

2010) (citing *Daubert*, 509 U.S. at 594, 596). Shaky but admissible evidence can be attacked by “vigorous cross-examination, presentation of contrary evidence, and careful instructions on the burden of proof.” *Daubert*, 509 U.S. at 596. Where the expert witness meets the criteria of Rule 702, the trial court has broad discretion whether to admit the evidence. *Id.* (finding juries should be given leave to act as a fact finder on the conclusions of an expert witness).

III. DISCUSSION

A. Dr. Lerner’s Opinion Is Relevant.

FRI argues that Dr. Lerner’s testimony should be excluded because it is irrelevant. (FRI’s Mot. 5:13-18, ECF No. 189.) The Court finds that each of Dr. Lerner’s four opinions are relevant to rebut the report and testimony of Dr. Wolver. As ORI correctly notes, FRI’s contentions relate to the weight of Dr. Lerner’s testimony rather than the admissibility. *See Clicks Billards, Inc. v. Sixshooters, Inc.*, 251 F.3d 1252, 1262-63 (9th Cir. 2001); *Prudential Ins. Co. of Am. v. Gibraltar Fin. Corp. of Cal.*, 694 F.2d 1150, 1156 (9th Cir. 1982). FRI disagrees with many of Dr. Lerner’s findings, but this does not affect the relevance of her testimony. *See Daubert*, 509 U.S. at 587 (quoting Fed. R. Evid. 401) (finding relevant evidence is anything that makes “the determination of the action more or less probable”).

First, FRI argues that Dr. Lerner’s opinion is irrelevant because she does not have an opinion “one way or another” about the efficacy of Lipozene compared to Propol. (FRI’s Mot. 5:13-18.) This mischaracterizes Dr. Lerner’s report and misconstrues the context of her findings. Dr. Lerner stated her opinion as to the effectiveness of Propol compared to Lipozene, by opining that the glucomannan in Lipozene is equivalent in viscosity to the glucomannan of the Propol tested in the Kaats Study. (Lerner Report Ex. 3, Ex. A at 9, 13, ECF No. 191-1.) The effectiveness of the glucomannan in Propol compared to Lipozene for weight loss is essential to the merits of this case because FRI contends that ORI mischaracterized the

effectiveness of Lipozene by using studies of Propol. (FRI's Answer & Countercl. ¶ 42, ECF No. 16.) Relevant evidence should be admitted for the trier of the fact to determine the merits of the case. *See Daubert*, 509 U.S. at 587. Therefore, Dr. Lerner's opinion as to the effectiveness of the glucomannan in Propol is relevant.

Second, FRI contends that Dr. Lerner's report is irrelevant because FRI disagrees with Dr. Lerner's conclusions about the viscosity needed for glucomannan to be effective.³ (FRI's Mot. 5:19-22.) In Dr. Wolver's report, he discussed the superiority of Propol over Lipozene, stating that there was a sustained viscosity of 100,000 cps for over 72 hours in a study on Propol. (Wolver Report Ex. 1 ¶¶ 12-13, ECF No. 189-3.) Dr. Lerner opined that Dr. Wolver failed to show that a viscosity of 100,000 cps sustained for 72 hours is necessary for glucomannan to be effective in weight loss. (Lerner Report 3.) The Court does not have to decide which scientific opinion has the "best provenance," rather the Court must determine if the testimony helps the trier of the fact understand the evidence. Fed. R. Evid. 702. Because a central issue of the case rests on whether ORI properly relied on the studies of Propol, Dr. Lerner's opinion regarding the viscosity of Propol is relevant.

Third, FRI argues that Dr. Lerner's opinion as to the materials in the Kaats Study compared to those of Lipozene is irrelevant. (FRI's Mot. 7:4-5.) Dr. Lerner opined that the Kaats Study was performed on the same active ingredients found in Lipozene. (Lerner Report 3.) If FRI disagrees with the definition of "active ingredients" or believes that the materials studied in the Kaats Study are not similar to Lipozene, this can be addressed by cross examining Dr. Lerner. *See Daubert*, 509 U.S. at 696.

In sum, FRI attempts to argue the correctness of Dr. Lerner's opinion rather than confronting Dr. Lerner's opinion on a relevance standard. This type of contention does not weigh on the admissibility of Dr. Lerner's opinion under the

³ Two of Dr. Lerner's opinions, both addressing glucomannan's viscosity, are substantially similar. (*See* ORI's Opp'n 11:4-13:8.) Thus, the Court analyzes the opinions together in this order.

1 applicable relevance standard. *See Ruiz-Troche v. Pepsi Cola*, 161 F.3d 77, 85 (1st
 2 Cir. 1998). Rather, this is an issue that FRI should confront during cross examination.
 3 *Daubert*, 509 U.S. at 596 (“Vigorous cross-examination, presentation of contrary
 4 evidence, and careful instruction on the burden of proof are the traditional and
 5 appropriate means of attacking shaky but admissible evidence.”). Thus, the Court
 6 concludes Dr. Lerner’s opinion is relevant.

7
 8 **B. Dr. Lerner Is Qualified To Render an Opinion.**

9 Dr. Lerner’s education and experience qualifies her to render an opinion on
 10 glucomannan, viscosity, and the chemical differences between Lipozene and Propol.
 11 (Lerner Report 1.) FRI contends that Dr. Lerner is not qualified because she has not
 12 served as an expert before, did not apply her expertise to the case, is not a medical
 13 doctor, and has not performed human clinical studies. (FRI’s Mot. 8:15-23.)

14 Dr. Lerner has a master’s degree in Chemical Engineering and a Ph.D. in
 15 Biomedical Engineering from John Hopkins University. (Lerner Report 1.) For the
 16 past 30 years, Dr. Lerner has analyzed biological molecules, “develop[ed] and
 17 validat[ed] assays” on the quality of active pharmaceutical ingredients, and compared
 18 chemical qualities of drugs, including the viscosity. (*Id.*) She is a trained chemical
 19 engineer and is qualified in both education and experience to discuss the differences
 20 between Lipozene and Propol. (*Id.*) Dr. Lerner is educated and experienced in the
 21 fields of chemistry and biology, and regularly compares drug products in her work.
 22 (*Id.*) If Dr. Lerner lacks the specialization of working with human subjects, this would
 23 affect the weight of testimony rather than the admissibility. *See In re Silicone Gel*
 24 *Breasts Implants Prods. Liab. Litig.*, 318 F. Supp. 2d 879, 889 (C.D. Cal. 2004)
 25 (holding arguments regarding expert’s qualifications go more towards weight than
 26 admissibility because jurors can determine who is “best” qualified).

27 Because Dr. Lerner has both the education and professional experience relating
 28 to the subject matter of this case, she is qualified to testify as an expert witness. *See*

1 *Thomas*, 42 F.3d at 1269 (finding qualifications of an expert witness should be
2 broadly construed). Any concerns regarding Dr. Lerner’s qualifications can be
3 addressed through cross examination. *See Daubert*, 509 U.S. at 596.

4
5 **C. Dr. Lerner Used Reliable Methods For Her Conclusions.**

6 FRI moves to exclude Dr. Lerner’s testimony and report on the grounds that
7 her monosaccharide and viscosity analysis was completed using unreliable methods.
8 (FRI’s Mot. 9:15, 11:14.) Dr. Lerner applied her specialized knowledge of chemical
9 and bioengineering to rebut Dr. Wolver’s contentions about the effectiveness of
10 Lipozene. (*See generally* Lerner Report.) Although Dr. Lerner compares studies she
11 did not conduct herself, such methods are permitted by the Federal Rules of
12 Evidence. *See* Fed. R. Evid. 703 (“An expert may base an opinion on facts or data in
13 the case that the expert has been made aware of or personally observed.”).

14 Dr. Lerner properly relies on existing independent research and publications
15 to draw her conclusions. *See Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1317
16 (9th Cir. 1995) (finding experts who base their conclusions on existing research are
17 less likely to be biased). FRI argues Dr. Lerner cannot “adequately compare and draw
18 conclusions from the various results” of the viscosity necessary for glucomannan to
19 be effective from the studies alone. (FRI’s Mot. 11:23-24.) Rather, FRI contends that
20 Dr. Lerner needs to know more information about the studies or conduct studies
21 herself. (FRI’s Mot. 13:3-5.) But expert witnesses do not have to conduct their own
22 experiments to be considered reliable. *See Daubert*, 43 F.3d at 1317. In fact, Dr.
23 Lerner’s reliance on previously existing studies suggest that her conclusion
24 “comports with the dictates of good science.” *See id.*

25 Moreover, this Court will not use FRI’s motion as a means to decide which
26 expert opinion is most correct. *See Daubert*, 43 F.3d at 1318 (finding the standard
27 for reliability is lower than that of correctness). The determination of correctness
28 should be left to the trier of the facts. *See id.* Dr. Lerner used her expertise to analyze

the chemical properties of Lipozene and Propol. (Lerner Report 1, 3.) Dr. Wolver, unlike Dr. Lerner, is not a chemist and applied appropriate methods for an expert with his qualifications as a medical doctor. (Wolver Report ¶ 2.) To rebut Dr. Wolver's opinions, Dr. Lerner is applying her technical background to the same information, using different methodologies than that of Dr. Wolver's. (Lerner Report 3, 13.) Although Dr. Lerner and Dr. Wolver used different methodologies for their respective analyses, this does not require the Court to conclude Dr. Lerner's methods are unreliable. *See* Advisory Committee Notes to Rule 702, 2000 Amendments; *see also Ruiz-Troche*, 161 F.3d at 85 (“*Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance.”). In sum, Dr. Lerner's report and testimony are admissible because she used reliable methods based on peer reviewed scientific studies.

IV. CONCLUSION & ORDER

For the foregoing reasons, the Court **DENIES** FRI's Motion to Exclude the Report & Testimony of Dr. Laura Lerner. Dr. Lerner is qualified because of her education and experience to testify on the subject matter of her report. The contents of Dr. Lerner's report are relevant to the case, and Dr. Lerner used reliable methods for her conclusions.

IT IS SO ORDERED.

DATED: March 29, 2017


Hon. Cynthia Bashant
United States District Judge